

# **EXHIBIT 92**

# **REDACTED**



To: Elizabeth Campbell  
Senior Counsel  
AmerisourceBergen Corporation

Date: July 27, 2012

Fm: Michael Mapes  
CSRA DEA Consultant

Re: ABC Order Monitoring Program Review  
July 23, 2012 - July 27, 2012

Attorney/Client Privileged Communication

#### PURPOSE OF REVIEW:

The review of the ABC Order Monitoring Program (OMP) was performed from July 23, 2012 to July 27, 2012. The review was conducted to ensure that the OMP is operating as expected and identify potential improvements to then OMP to ensure that the system is in compliance with 21 CFR § 1301.74 (b) and ABC policies and procedures.

#### DOCUMENTS REVIEWED AND ABC EMPLOYEES INTERVIEWED:

The review included a review of several New Customer Due Diligence (NCDD) files, review of ABC SOM policies and procedures, the default threshold for each drug family and customer size for retail pharmacies, the ABC Do Not Ship List, and several specific drug reports.

The review included discussions with Ed Hazewski, Joe Tomkiewicz, and Kevin Kreutzer. Many of the discussions related to the OPM centered around the need to completely document all aspects of decisions that are made related to customer orders.

#### PREVIOUS REVEIW OF THE ABC OMP:

The last review conducted of the OMP was completed on November 5, 2010. The review included five recommendations for changes to the OPM. Although the changes were considered, there was no documentation created to address each of the recommendations and the changes made or considered in relation to each of the recommendations.

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[REDACTED]

## REVIEW OF SPECIFIC ACCOUNTS

A review of monthly reports provided for hydromorphone and oxycodone were used to identify specific accounts for additional review. Below are the accounts selected and the results of the review of each account.

### ██████████ and ██████████ (Orlando, FL Area)

Both of the pharmacies are owned by the same individuals, ██████████. Each of the pharmacies was opened with ABC at about the same time, September 1, 2011. The pharmacies are ranked 16th & 19th for purchases of hydromorphone products from ABC in June of 2012.

██████████ showed a 467% increase in purchases of hydromorphone between April, May and June of 2012 as compared to October, November, and December of 2011. ██████████ showed a 681% increase for the same time period for purchases of hydromorphone products. In June of 2012 Metro Pharmacy purchased 8,100 dosage units of hydromorphone products and Metro RX purchased 7,600 dosage units.

Both pharmacies are small sized, based on dollar volume. The default threshold for small sized retail pharmacies for hydromorphone solids (HD) is ██████████ dosage units.

██████████ of the purchases from ABC by ██████████ are controlled substances and ██████████ of the purchases from ABC by ██████████ are controlled substances.

A review of the ABC OMP and a report of the sales invoices to both ██████████ and ██████████ shows that the OMP program identified orders which placed the purchases for each of the pharmacies above the threshold limits and that those orders were reviewed appropriately by ABC personnel.

### ██████████ Stow, Ohio

According to the 590 completed in November of 2011, ██████████ is a closed door pharmacy located in a medical office building in Stow, Ohio. The pharmacy is owned by the doctors who also own and prescribe controlled substances at ██████████. The 590 showed that the anticipated monthly use of oxycodone combination products was ██████████; hydrocodone combination products ██████████; methadone ██████████; and alprazolam ██████████.

The 590 acknowledges that the pharmacy is unique in that the doctor who prescribe the drugs are the owners of the pharmacy and the employees of the pharmacist who fills the prescriptions.

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██████████.

The 590 advises that the pharmacy does not have a web site and that the pharmacy is required to notify ABC immediately upon establishing a web site. A review of the Internet on 7-26-2012 shows that the pharmacy is part of the website for [REDACTED]  
[REDACTED] No drug products were offered for sale through the web site.

[REDACTED] is ranked as the 10th largest purchaser of hydromorphone products for independent pharmacies from ABC for the period of January of 2012 through June of 2012. The sales of hydromorphone products have to SPS have increased 99% between the periods of October through December of 2011 and April through June of 2012. The thresholds for SPS have been raised to account for larger purchases. The threshold for oxycodone solids is [REDACTED] the current threshold for oxycodone 30mg solids is [REDACTED] and their current threshold for morphine solids is [REDACTED]

Prior to the opening of [REDACTED] many of the prescriptions from the [REDACTED] [REDACTED] were filled at [REDACTED] in Stow, OH. Since the [REDACTED] has opened, the volume of pain related controlled substances purchased from ABC by [REDACTED] have decreased significantly.

With the adjusted thresholds for pain management products, orders from [REDACTED] have not hit the OMP in recent months.

#### **[REDACTED] Clinton, TN**

[REDACTED] of Clinton, TN was opened by ABC in March of 2004. The account has been set as a large customer based on dollar volume. Based on the last month sales as shown on the January through June 2012 report, the customer should be a medium sized customer.

A medium customer for oxycodone 30mg has a threshold of [REDACTED] dosage units a month. [REDACTED] purchased [REDACTED] dosage units in April of 2012, [REDACTED] dosage units in May of 2012 and [REDACTED] dosage units in June of 2012.

Of the purchases by [REDACTED] from ABC 36.9% are for controlled substances.

There were [REDACTED] reports of orders from [REDACTED] that hit the ABC OMP in the past two months. This is a significant issue in that ABC has set thresholds for specific products and reports orders above those thresholds to DEA a suspicious orders. When the business size is improperly set, customers may order above the thresholds and sales that should be considered as suspicious are made and no report to DEA is made.

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[REDACTED]

## CONCLUSION:

The review of the ABC OMP demonstrated that the OMP is generally performing the functions that it was designed to perform. ABC has designed and is operating a system that identifies suspicious orders for controlled substances and ABC is reporting those suspicious orders to DEA upon discovery.

Ongoing efforts must be made by ABC to ensure that the OMP is capturing all intended orders and that the orders are being reported to DEA. The efforts to document all decisions made in relation to releasing or canceling orders, as well as threshold need to be strengthened and standardized.

## RECOMMENDATIONS:

1. Review the recommendations from reviews of the OMP and document the discussions and changes made as a result of the review.
2. In addition to obtaining information from pharmacies concerning the prescribers for which the pharmacy is filling prescriptions, provide pharmacies with guidance for pharmacies to identify and mitigate the risk associated with the dispensing of controlled substances.
3. Add a question to the CSRA 590 to determine if pharmacies have a valid DEA self-certification to sell a scheduled listed chemical product as required in 21 CFR § 1314.40.
4. Perform a regularly scheduled review to determine if the customers are set at the proper size in the OPM based on current dollar volume of purchases by the customer.
5. Work to enhance documentation and standardization of decisions related to orders that are held, released and for changes in thresholds.

Should you have questions concerning this matter, please contact me at

[REDACTED] or [REDACTED]

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